

1.825.99

Case Docket No. _____

JC584 U.S. PRO
 09/432350
 11/02/99

For: **A SINGLE USE LANCET ASSEMBLY**

 X 1 sheet(s) of drawings.

An assignment of the invention to: _____

Certified copy(ies) of the following application(s), the priority of which is hereby claimed under 35 USC §119:

X A verified statement to establish small entity status under 37 C.F.R. 1.9 and 37 CFR 1.27.

<u>Small Entity</u>	<u>Other Than A Small Entity</u>
---------------------	--------------------------------------

	No. Filed	No. Extra	Rate	Fee	Rate	Fee
Basic Fee				\$380		\$760
Total Claims	25	- 20 = 5	x 9 =	45	x 18 =	
Independent claims	2	- 3 = 0	x 39 =		x 78 =	
_____ Multiple claims presented			x 130 =		x 260 =	
_____ Non-English language			x =		x =	
			Total \$	425	Total \$	

- [] Please charge my Deposit Account No. _____ in the amount of \$_____.
[] A duplicate copy of this sheet is enclosed.
[X] A check in the amount of \$ 425.00 to cover the filing fee is enclosed.
[] The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.
[] Any additional filing fees required under 37 CFR 1.16.
[] Any patent application processing fees under 37 CFR 1.17.
[] The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.
[] Any filing fees under 37 CFR 1.16 for presentation of extra claims.
[] Any patent application processing fees under 37 CFR 1.17.
[] The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of Allowance pursuant to 37 CFR 1.311(b).

11-2-99
Date

James E. Wetterling, Jr.	Jennie S. Malloy
Reg. No. 31,440	Reg. No. 37,670

Peter A. Matos
Reg. No. 37,884

FOR: MALLOY & MALLOY, P.A.
2800 S.W. Third Avenue
Historic Coral Way
Miami, Florida 33129
(305) 858-8000

NC59/1.825.99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steven Schraga

Serial No.:

Filing Date: November 2, 1999

For: A SINGLE USE LANCET ASSEMBLY

2800 S.W. Third Avenue
Historic Coral Way
Miami, Florida 33129
November 2, 1999

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

Dear Sir:

CERTIFICATE OF EXPRESS MAILING

I HEREBY CERTIFY that this correspondence is being deposited by United States Express Mail, Label No. EL-053-332-472-US, in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, this 2nd day of November, 1999.

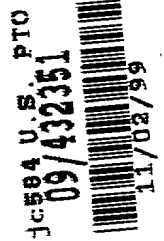
Respectfully submitted,

MALLOY & MALLOY, P.A.
2800 S.W. Third Avenue
Historic Coral Way
Miami, Florida 33129
(305) 858-8000

By: 

Peter A. Matos
Reg. No. 37,884

Date: 11-2-99



09432351 11/02/99

INDEPENDENT INVENTOR - SMALL ENTITY STATUS

Applicant or Patentee: Steven Schraga Attorney's
 Serial or Patent No.: _____ Docket No.: 1.825.99
 Filed or Issued: _____
 For: A SINGLE USE LANCET ASSEMBLY

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
 STATUS (37 CFR 1.9(f) and 1.27(b) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled,

A SINGLE USE LANCET ASSEMBLY
 described in

☒ the specification filed herewith.
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ no such person, concern or organization
☐ person, concerns, or organization listed below *

*Note: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____
 ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
 ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statement were made with the under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR
STEVEN SCHRAGA

NAME OF INVENTOR

NAME OF INVENTOR

Signature of inventor

Date

Date

Date

November 1, 1999

A SINGLE USE LANCET ASSEMBLY

BACKGROUND OF THE INVENTIONField of the Invention

The present invention relates to a single use lancet assembly which is substantially compact, yet effective for piercing a patient's finger or other body part to obtain a blood sample. The single use lancet device is further configured to be substantially safe to transport and to ensure that subsequent uses of a contaminated lancet tip cannot occur.

Description of the Related Art

Lancets are commonly utilized instruments which are employed both in hospitals and other medical facilities, as well as by private individuals, such as diabetics, in order to prick or pierce a patient's skin, typically on a finger of a patient, thereby leading to the generation of a blood sample which can be collected for testing. Because of the wide spread use of such lancets, there are a variety of lancet devices which are available for utilization by patients and/or practitioners in a variety of different circumstances.

For example, a typical lancet may merely include a housing with a sharp piercing tip that is pushed into the patient's skin. More commonly, however, lancet devices, which house a

1 piercing tip and/or a lancet, have been developed which
2 effectively encase and fire the lancet into the patient's skin,
3 thereby eliminating the need for the person taking the sample to
4 actually push the lancet tip into the skin.

5 Within the various types of specialized lancet devices, one
6 variety are typically configured for multiple and/or repeated
7 uses, while another category is particularly configured for
8 single use, after which the entire device is disposed of.
9 Looking in particular to the single use, disposable lancet
10 devices, such devices typically include a housing which contains
11 and directs or drives a piercing tip into the patient's skin,
12 and which is disposed of along with the used lancet. Naturally,
13 so to make such disposable devices cost effective for frequent
14 use, such devices tend to be rather simplistic in nature
15 providing only a sufficient mechanism for firing, and not overly
16 complicating the design so as to minimize that cost.

17 While existing single use devices are generally effective
18 for achieving the piercing of the skin required for effective
19 operation, such single use, disposable devices typically do not
20 incorporate a large number of safety features to ensure the safe
21 use and disposal of the device. For example, one primary area
22 of safety which must be addressed with all lancet devices
23 pertains to the purposeful and/or inadvertent reuse of a
24 contaminated lancet. Unfortunately, most currently available
25 single use lancet devices are configured such that after a use

thereof has been achieved, it is possible for a patient to re-cock the device, thereby allowing for a subsequent, inappropriate use.

As a result, it would be highly beneficial to provide a single use lancet device which is substantially compact and disposable, can be manufactured in a substantially cost effective manner, and which nevertheless is substantially safe to utilize, affirmatively preventing re-use, once contaminated.

SUMMARY OF THE INVENTION

The present invention relates to a single use lancet device configured to pierce a patient's skin and be useable only a single time, thereby preventing reuse of a contaminated lancet piercing tip. In particular, the present single use lancet device includes a housing having an open interior area and an access opening defined therein. The housing is preferably compact and includes a lancet disposed within its open interior.

Looking to the lancet, it is preferably of the type which includes a body and a piercing tip. It is the piercing tip which includes the pointed configuration structured to penetrate or pierce a patient's skin for the drawing of blood. Moreover, the lancet is cooperatively disposed within the open interior of the housing such that the lancet may move between at least a cocked orientation and a piercing orientation wherein the patient's skin is penetrated by the piercing tip.

Also operatively associated with the lancet is a driving assembly. The driving assembly is structured to move or drive the lancet, at least temporarily, into the piercing orientation from the cocked orientation. Preferably, however, the device is configured such that the cocked orientation is generally maintained until affirmatively released by a user. Along these lines, the present single use lancet device also includes an actuation button operatively associated with the lancet. The actuation button is structured to protrude from the housing, at least when the lancet is disposed in the cocked orientation, so as to be effectively actuatable. When the lancet is in the cocked orientation, the actuation assembly maintains the lancet in that cocked orientation, however, when it is actuated, such as by being pushed inward, the lancet is released from the cocked orientation and the driving assembly propels the lancet at least temporarily into its piercing orientation wherein the piercing tip protrudes through the access opening of the housing.

In order to ensure that lancet device can only be used a single time, the present single use lancet device further includes abutment structure cooperatively disposed between the housing and the lancet. The abutment structure is configured to prevent the lancet from moving into the cocked orientation after movement into the piercing orientation. Preferably, the abutment structure includes a shoulder element and a restrictor

1 panel operatively associated with the lancet and the housing.
2 In particular, the shoulder element is structured to pass over
3 the restrictor panel when the lancet moves from its cocked
4 orientation to its piercing orientation. Conversely, however,
5 when a user attempts to move the lancet back into the cocked
6 orientation after it moved into the piercing orientation, the
7 restrictor panel abuts the shoulder element preventing further
8 movement. As a result, movement of the lancet into the cocked
9 orientation is prevented once the lancet has been used a single
10 time, and subsequent uses of a contaminated lancet are
11 prevented.

BRIEF DESCRIPTION OF THE DRAWINGS

12
13
14 For a fuller understanding of the nature of the present
15 invention, reference should be had to the following detailed
16 description taken in connection with the accompanying drawings
17 in which:

18 Figure 1 is a perspective illustration of an embodiment of
19 the single use lancet device of the present invention;

20 Figure 2 is a side cross section view of the single use
21 lancet device of the present invention in an unused, initially
22 un-cocked orientation;

23 Figure 3 is a side cross section view of the single use
24 lancet device of the present invention in a cocked orientation;

25 Figure 4 is a side cross section view of the single use

lancet device of the present invention after it has moved into a piercing orientation from the cocked orientation;

Figure 5 is a front cross section view of the single use lancet device of the present invention; and

Figure 6 is a side cross section view of another embodiment of the single use lancet device of the present invention after the lancet has moved from the cocked orientation through the piercing orientation.

Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Shown throughout the Figures, the present invention is directed towards a single use lancet device, generally indicated as 10. In particular, the single use lancet device 10 of the present invention includes a housing, generally indicated as 20. The housing 20 is preferably substantially small and compact, and may be made of one or a plurality of segments, preferably of a generally rigid, disposable material, such as plastic. The housing 20 includes an at least partially opened interior 28 and at least one access opening 22 defined therein. The open interior 28 of the housing 20 is preferably sized and configured to effectively receive a lancet, generally 30 therein.

In particular, the lancet device 10 of the present invention also comprises a lancet 30. The lancet 30 preferably

1 includes a body 32 and a piercing tip 34. The piercing tip 34
2 is what will be used to pierce a person's skin so as to draw
3 blood to be utilized for a sample and or test procedure.
4 Moreover, the body 32 may be the shaft of the piercing tip 34
5 and/or an additional structure such as that depicted in the
6 figures. Regardless, however, the lancet 30 is structured to
7 move within the open interior 28 of a housing 20, preferably at
8 least between a cocked orientation, as depicted in Figure 3, and
9 a piercing orientation wherein the piercing tip 34 of lancet 30
10 at least temporarily protrudes through the access opening 22.

11 Looking in further detail to the illustrated lancet device
12 10, and the path of movement of the lancet 30 within the housing
13 20, when the lancet device 10 is initially obtained for use, the
14 lancet 30 is preferably maintained in an un-used, initially un-
15 cocked and pre-fired orientation, as best seen in Figure 2. In
16 this initially un-cocked and pre-fired orientation a protective
17 cover 40 preferably extends into the open interior 28 of the
18 housing 20 so as to at least partially and removably cover the
19 piercing tip 34 of the lancet 30, thereby maintaining the safety
20 and sterility of the piercing tip 34 when not being used. In
21 this regard, the protective cover 40 may be formed from a
22 variety of preferably rigid materials and is structured to
23 protrude from the housing 20. Furthermore, the protective cover
24 40 may include an enlarged head 42 configured to facilitate
25 grasping thereof.

1 Preferably utilizing the protective cover 40, the
2 protective cover 40 is structured to be pushed inwardly into the
3 housing by a user, as depicted by the arrows on Figure 2,
4 thereby pushing the lancet 30 further into the housing 20. Such
5 pushing of the lancet 30 into the housing 20 results in a
6 positioning of the lancet 30 in its cocked orientation, best
7 illustrated in Figure 3. Once in the cocked orientation, the
8 protective cover 40 is then structured to be removable from the
9 piercing tip 34, such as by a twisting thereof, thereby leaving
10 the piercing tip 34 complete exposed for use.

11 The single use lancet of the present invention further
12 includes a driving assembly, generally 38. The driving assembly
13 38 is particularly configured to move the lancet 30 at least
14 temporarily into its piercing orientation wherein the piercing
15 tip 34 protrudes through the access opening 22 of the housing 20
16 a desired amount. In particular, if desired a depth adjustment
17 structure could be positioned at the access opening to control
18 the amount which the piercing tip protrudes from the housing 20.
19 For example, a threaded washer type element could be adjustably
20 secured to the housing 20 in generally surrounding relation to
21 the access opening 22.

22 Looking further to the driving assembly, preferably the
23 driving movement occurs when the lancet 30 is released from its
24 cocked orientation. In the illustrated embodiment, the driving
25 assembly 38 includes a biasing element operatively disposed

1 between the lancet 30 and the housing 20. Moreover, in the
2 illustrated embodiment a spring is preferably utilized, however,
3 it is recognized that a variety of other driving assemblies can
4 be utilized, including a wedge assembly, a hammer type assembly
5 and/or a resilient material plate, segment or extension, all of
6 which may be configured to move the lancet 30 from the cocked
7 orientation into the piercing orientation. Further, it is
8 preferred that based upon the sizing of the housing 20 and the
9 nature and size of the driving assembly 38, that after the
10 lancet 30 has moved into the piercing orientation wherein the
11 piercing tip 34 protrudes through the access opening 22, the
12 lancet tends to be retracted back into the housing, as best
13 illustrated in Figure 4. As a result, the used piercing tip 34
14 is effectively concealed within the housing 20 subsequent to
15 usage, protecting against inadvertent engagement between a
16 person and the used piercing tip 34.

17 In order to retain, and subsequently effectively release
18 the lancet 30 from its cocked orientation, the single use lancet
19 10 of the present invention further includes an actuation
20 assembly, generally, 50. Although a variety of different
21 actuation assemblies may be incorporated so as to retain and
22 then release the lancet 30 from its cocked orientation, which in
23 the illustrated embodiment allows the driving assembly to be
24 released from its compressed orientation, the actuation assembly
25 50 includes an actuation button 52. In the illustrated

embodiment, the actuation button 52 is structured to at least temporarily protrude from the housing 20, such as through an actuation aperture 24. Furthermore, the actuation button 52 is preferably secured, either directly or indirectly to the lancet 30, so as to generally restrict movement of the lancet 30 from the cocked orientation when it protrudes from the housing 20. As a result, the cocked orientation is maintained while the actuation button protrudes from the housing 20. Specifically, in the illustrated embodiment, the actuation button 52 extends from the body 32 of the lancet 30 by a biased segment, and as such, by abutting the housing 20 within the actuation opening 24, movement of the lancet 30 from the cocked orientation is prevented. When, however, the actuation button 52 is actuated, such as by being pushed inwardly, into the housing, it is at least temporarily concealed within the housing 20, removing the abutting engagement and allowing the lancet 30 to freely move within the housing 20, at least temporarily into the piercing orientation. Although the preceding defines the illustrated actuation assembly, it is understood that a variety of alternative actuation assemblies, such as including separate elements to retain and to release the lancet may also be provided, and or including structures which are actually part of the driving assembly, may also be provided.

Looking in particular to Figure 5, movement of the lancet 30 through the housing 20 is preferably maintained in a

1 substantially linear path by a guide assembly. In the
2 illustrated embodiment, the guide assembly includes at least one
3 guide ridge 33 protruding from the body 32 of the lancet 30, and
4 at least one corresponding guide track 25 structured to movably
5 receive the guide ridge 33 therein. The guide track 25
6 preferably extends at least partially along a length of the open
7 interior 28 of the housing 20 so as to maintain the guide ridge
8 33 effectively therein during a necessary range of motion of the
9 lancet 30. As depicted in Figure 5, preferably a pair of guide
10 ridges 33 are disposed on opposite sides of the lancet body 32,
11 with a corresponding pair of oppositely disposed guide tracks 25
12 being defined in the housing. It is of course, however,
13 understood that the guide tracks 25 need not necessarily be
14 directly defined in the housing 20, but may be additional
15 elements secured therein, and conversely the guide track(s) may
16 be defined in or on the lancet body 32, with the guide ridge(s)
17 extending inwardly from the housing 20.

18 The single use lancet 10 of the present invention further
19 includes a restrictor assembly, generally 60. The restrictor
20 assembly 60 is structured to substantially prevent the lancet 30
21 from moving back into the cocked orientation of Figure 3 after
22 it has moved, even momentarily, into the piercing orientation
23 wherein a patient's skin may be pierced and the piercing tip 34
24 become contaminated. In particular, the restrictor assembly 60
25 is structured such that when the lancet 30 is disposed in the

1 initially un-cocked orientation, as best seen in Figure 2,
2 movement of the lancet 30 back into the cocked orientation can
3 effectively result despite the restrictor assembly 60. After,
4 however, the lancet 30 has moved into its piercing orientation
5 wherein the piercing 34 has protruded through the access opening
6 22 of the housing 20, the restrictor assembly is configured such
7 that the lancet 30 can no longer be pushed back into the cocked
8 orientation. As a result, a patient, can neither accidentally
9 nor purposefully reuse the single use lance 10 of the present
10 invention after it has been fired.

11 In the illustrated embodiment, the restrictor assembly 60
12 includes an abutment structure cooperatively disposed between
13 the housing 20 and the lancet 30. The abutment structure is
14 configured to physically prevent movement of the lancet back
15 into the cocked orientation. Preferably, the abutment structure
16 comprises a shoulder element 62 and a restrictor panel 64
17 configured to freely pass one another when the lancet 30 moves
18 from the cocked orientation to the piercing orientation, but
19 also configured to abut one another upon attempted movement of
20 the lancet 30 back into the cocked orientation after it has
21 moved into the piercing orientation. Looking to Figure 4, the
22 illustrated shoulder element 62 includes an at least partially
23 slopped and preferably biased configuration, such as an elongate
24 biased finger that at least partially retracts inward towards
25 the body 32 of the lancet 30 so as to facilitate passage thereof

1 past the restrictor panel 64. In this regard, preferably mating
2 slopped surfaces are provided on the shoulder element 62 and the
3 restrictor panel 64, thereby facilitating the slided passages
4 past one another, and indeed, promoting an at least partial
5 retraction of the shoulder element 62 to further facilitate this
6 passage past one another, upon movement of the lancet 30 in a
7 first direction towards the access opening 22 of the housing 20.
8 The shoulder element 62 is also, however, structured to
9 generally expand after it has passed the restrictor panel 64,
10 such as back into its normal unretracted and/or un-compressed
11 orientation, such that it will abut the restrictor panel 64 upon
12 attempted movement of the lancet 30 in a second direction
13 opposite the access opening 22 of the housing 20.

14 Although an opposite configuration could be just as
15 effectively utilized, in the illustrated embodiment, the biased
16 finger 62 of the shoulder element extends from the lancet 30,
17 preferably generally toward the piercing tip 34 of the lancet
18 30., while the restrictor panel 64 protrudes from the housing
19 20, extending into the open interior 28 of the housing 20.
20 Along these lines, the restrictor panel 64 includes a protruding
21 element preferably with the aforementioned slopped configuration
22 which downwardly slopes away from the piercing tip 34 of the
23 lancet 30 facilitating the aforementioned slided passage past
24 the shoulder element 62.

25 So as to provide generally secure movement restriction

1 through effective abutment, both the shoulder element 62 and the
2 restrictor panel 64 each preferably include abutment surfaces 63
3 and 65, respectably. The abutment surfaces 63 and 65 are
4 structured to generally engage and abut one another, as best
5 illustrated in Figure 4, thereby preventing movement of the
6 lancet 30 back into the cocked orientation. In the illustrated
7 embodiment, the abutment surfaces 63, 65 are generally flat,
8 although it is recognized that interlocking fingers or wedges,
9 and/or other types of engaging structures that prevent relative
10 movement in at least one direction could also be effectively
11 utilized.

12 Addressing further the restrictor assembly of the present
13 invention, it is understood that a variety of different
14 restrictor assemblies may be effectively utilized which prevent
15 movement of a lancet 30 back into a cocked orientation after the
16 lancet 30 has moved sufficiently forward and/or has moved into
17 the piercing orientation. As such, the embodiment illustrated
18 in Figures 2 through 5 is merely a single illustration of a
19 preferred contemplated embodiment, and other alternative
20 embodiments are also considered within the scope of the
21 restrictor assembly of the present invention. By way of
22 example, and looking specifically to Figure 6, the actuation
23 button 52 itself may comprise part of the restrictor assembly.
24 In such an embodiment, a restrictor panel 25 is defined in the
25 housing 20, and the actuation button 52 as part of the biased

1 finger of the shoulder element, includes an abutment surface 54
2 which engages a confronting surface of the restrictor panel 25.
3 In such an embodiment, the initially un-cocked orientation
4 provides for the actuation button 52 to be initially disposed
5 rearward of the restrictor panel 25 so as to permit movement of
6 the lancet 30 at least initially into the cocked orientation.
7 Moreover, in this embodiment, the previous embodiment, and/or
8 any other alternative embodiment, if desired, the protective
9 cover 40 may be equipped with an interior shield segment or
10 other configuration which extends into the housing and maintains
11 the biased finger of the shoulder element 62, or another
12 component of the restrictor assembly, in a generally compressed
13 and/or retracted orientation until the protective cover 40 is
14 removed. As a result, in such an embodiment, so long as the
15 protective cover 40 is maintained on the piercing tip 34, the
16 lancet 30 is always able to return the cocked orientation.
17 Preferably, however, re-positioning of the protective cover onto
18 the piercing tip in such a manner as to be able to "reset" the
19 lancet 30, allowing to move once again into the cocked
20 orientation will be prevented.

21 Since many modifications, variations and changes in detail
22 can be made to the described preferred embodiment of the
23 invention, it is intended that all matters in the foregoing
24 description and shown in the accompanying drawings be
25 interpreted as illustrative and not in a limiting sense. Thus,

1 the scope of the invention should be determined by the appended
2 claims and their legal equivalents.

3 Now that the invention has been described,

1 What is claimed is:

2 1. A single use lancet device comprising:

3 a housing, said housing including an at least partially
4 open interior and an access opening defined therein;

5 a lancet, said lancet including a body and a piercing tip;
6 said lancet disposed in said open interior of said housing
7 and structured to move at least between a cocked orientation and
8 a piercing orientation;

9 a driving assembly structured to move said lancet at least
10 temporarily into said piercing orientation; and

11 a restrictor assembly structured to substantially prevent
12 said lancet from moving into said cocked orientation after said
13 lancet has moved at least temporarily into said piercing
14 orientation.

15 2. A single use lancet as recited in claim 1 wherein said
16 driving assembly includes a biasing element operatively disposed
17 between said lancet and said housing.

18 3. A single use lancet as recited in claim 2 wherein said
19 biasing element comprises a spring.

20 4. A single use lancet as recited in claim 1 further
21 comprising an actuation assembly structured to release said
22 lancet from said cocked orientation.

23 5. A single use lancet as recited in claim 4 wherein said
24 actuation assembly comprises a button structured to at least
25 temporarily protrude from said housing when said lancet is

1 disposed in said cocked orientation.

2 6. A single use lancet as recited in claim 5 wherein said
3 button is secured to said lancet and is structured to abut said
4 housing when protruding therethrough so as to retain said lancet
5 in said cocked orientation until disengaged from said abutting
6 engagement.

7 7. A single use lancet as recited in claim 6 wherein said
8 button is structured to be at least temporarily concealed by
9 said housing after said lancet has moved out of said cocked
10 orientation.

11 8. A single use lancet as recited in claim 1 wherein said
12 restrictor assembly comprises and abutment structure
13 cooperatively disposed between said housing and said lancet and
14 structured to prevent said lancet from moving into said cocked
15 orientation after movement into said piercing orientation.

16 9. A single use lancet as recited in claim 8 wherein said
17 abutment structure comprises a shoulder element and a restrictor
18 panel, said restrictor panel and said shoulder element
19 structured to pass one another upon said lancet moving from said
20 cocked orientation to said piercing orientation, and to abut one
21 another upon attempted movement of said lancet into said cocked
22 orientation after movement into said piercing orientation.

23 10. A single use lancet as recited in claim 9 wherein said
24 shoulder element includes a sloped, at least partially biased
25 configuration structured to at least partially retract to

1 facilitate passage of said restrictor panel and said shoulder
2 element past one another in a first direction corresponding
3 movement of said lancet from said cocked orientation to said
4 piercing orientation, and to expand subsequent said passage past
5 one another in said first direction such that said shoulder
6 element and said restrictor panel abut one another upon movement
7 towards one another in a second direction generally opposite
8 said first direction.

9 11. A single use lancet as recited in claim 9 wherein said
10 shoulder element comprises a biased finger extending from said
11 lancet, and said restrictor panel comprises a protruding element
12 protruding from said housing.

13 12. A single use lancet as recited in claim 11 wherein
14 said protruding element includes a sloped configuration which
15 downwardly slopes away from said piercing tip of said lancet so
16 as to facilitate passage thereof past said biased finger upon
17 said lancet moving in a first direction towards said access
18 opening.

19 13. A single use lancet as recited in claim 12 wherein
20 said biased finger comprises an actuation button structured to
21 release said lancet from said cocked orientation.

22 14. A single use lancet as recited in claim 1 further
23 comprising a guide assembly operatively disposed between said
24 lancet and said housing and structured to guide a substantially
25 linear movement of said lancet through said housing.

1 15. A single use lancet as recited in claim 14 wherein
2 said guide assembly comprises at least one guide ridge
3 protruding from said body of said lancet, and at least one
4 corresponding guide track structured to movably receive said
5 guide ridge therein and extending at least partially along a
6 length of said open interior of said housing.

7 16. A single use lancet as recited in claim 1 further
8 comprising a protective cover structured to at least partially
9 and removably cover said piercing tip of said lancet at least
10 prior to movement of said lancet into said cocked orientation.

11 17. A single use lancet as recited in claim 16 wherein
12 said protective cover is structured to protrude from said access
13 opening of said housing and is structured to be pushed by a user
14 so as to position said lancet into said cocked orientation.

15 18. A single use lancet device comprising:

16 a housing, said housing including an at least partially
17 open interior and an access opening defined therein;

18 a lancet, said lancet including a body and a piercing tip;
19 said lancet disposed in said open interior of said housing
20 and structured to move at least between a cocked orientation and
21 a piercing orientation;

22 a driving assembly structured to move said lancet at least
23 temporarily into said piercing orientation;

24 a shoulder element and a restrictor panel operatively
25 associated with said lancet and said housing, said shoulder

1 element structured to pass over said restrictor panel upon said
2 lancet moving from said cocked orientation to said piercing
3 orientation, and to abut said restrictor panel upon attempted
4 movement of said lancet into said cocked orientation after
5 movement into said piercing orientation so as to substantially
6 prevent said lancet from moving into said cocked orientation
7 after said lancet has moved at least temporarily into said
8 piercing orientation; and

9 an actuation button structured to at least temporarily
10 protrude from said housing when said lancet is disposed in said
11 cocked orientation so as to maintain said lancet in said cocked
12 orientation.

13 19. A single use lancet as recited in claim 18 wherein
14 said shoulder element comprises said actuation button.

15 20. A single use lancet as recited in claim 18 wherein
16 said shoulder element extends from said lancet and said
17 restrictor panel is at least partially secured to said housing.

18 21. A single use lancet as recited in claim 18 further
19 comprising a protective cover structured to at least partially
20 and removably cover said piercing tip of said lancet at least
21 prior to movement of said lancet into said cocked orientation.

22 22. A single use lancet as recited in claim 21 wherein
23 said protective cover is structured to protrude from said access
24 opening of said housing and is structured to be pushed by a user
25 so as to position said lancet into said cocked orientation.

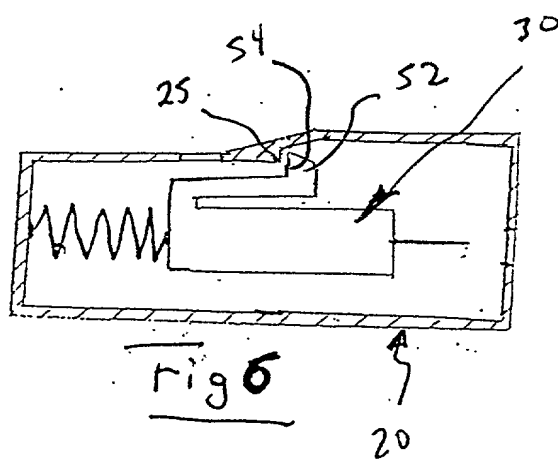
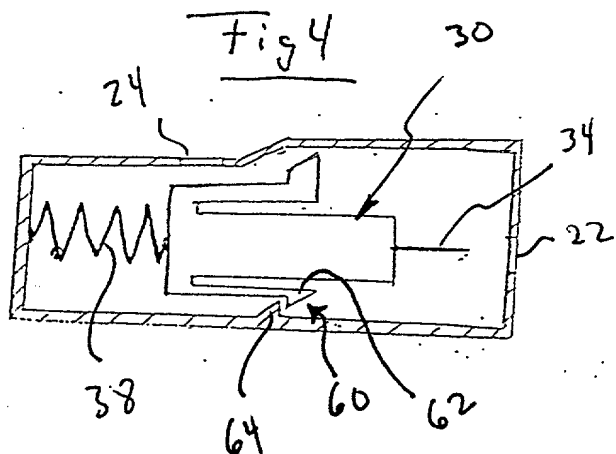
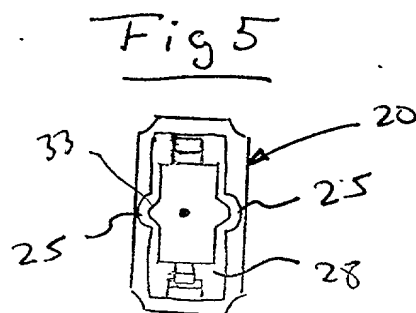
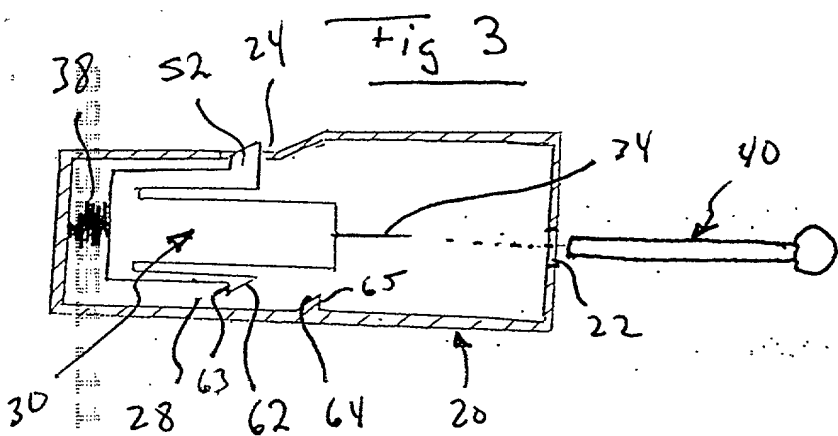
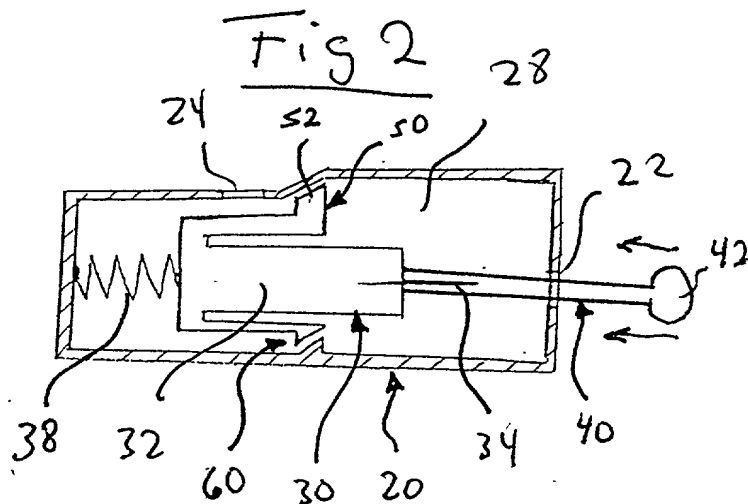
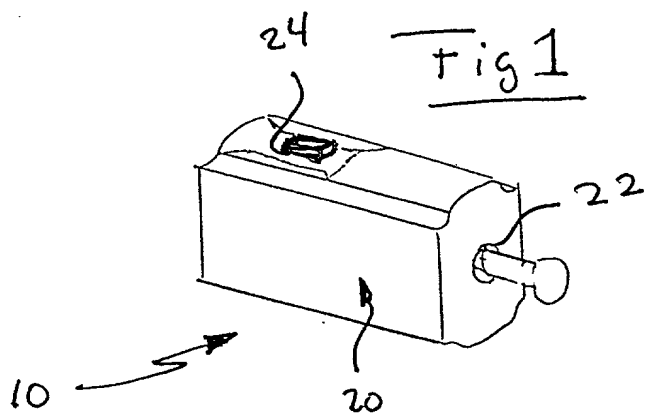
1 23. A single use lancet as recited in claim 18 wherein
2 said shoulder element comprises a biased finger extending from
3 said lancet generally towards said piercing tip of said lancet,
4 and said restrictor panel comprises a protruding element
5 disposed in said housing.

6 24. A single use lancet as recited in claim 23 wherein
7 said protruding element includes a sloped configuration which
8 downwardly slopes away from said piercing tip of said lancet so
9 as to facilitate passage thereof past said biased finger upon
10 said lancet moving in a first direction towards said access
11 opening.

12 25. A single use lancet as recited in claim 18 further
13 comprising at least one guide ridge protruding from said body of
14 said lancet, and at least one corresponding guide track
15 structured to movably receive said guide ridge therein and
16 extending at least partially along a length of said open
17 interior of said housing so as to guide substantially linear
18 movement of said lancet within said housing.

Abstract of the Disclosure

A single use lancet device having a housing, with an open interior and an access opening defined therein, a lancet, with a body and a piercing tip, and disposed in the open interior of the housing so as to move between a cocked orientation and a piercing orientation, a driving assembly structured to move the lancet into the piercing orientation, and a restrictor assembly having a shoulder element and a restrictor panel operatively associated with the lancet and the housing and structured to pass over the restrictor panel upon the lancet moving from its cocked orientation to its piercing orientation, and to abut the restrictor panel upon attempted movement of the lancet back into its cocked orientation after movement into the piercing orientation, thereby preventing the lancet from moving back into the cocked orientation and preventing re-use of a contaminated piercing tip.



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

English Language Division

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A SINGLE USE LANCET ASSEMBLY

the specification of which

(check one)

☒ is attached hereto

_____ was filed on _____ as

Application Serial No. _____

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate have a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s) Priority
Claimed

(Number) (Country) (Day/Month/Year Filed) Yes No _____

(Number) (Country) (Day/Month/Year Filed) Yes No _____

(Number) (Country) (Day/Month/Year Filed) Yes No _____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national PCT International filing date of this application:

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made of information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

James E. Wetterling - Reg. No. 31,440

Jennie S. Malloy - Reg. No. 37,670

Peter A. Matos - Reg. No. 37,884

Send correspondence to:

MALLOY & MALLOY, P.A.
2800 S.W. Third Avenue
Historic Coral Way
Miami, Florida 33129

Direct telephone calls to:

(305) 858-8000

Full name of sole or first inventor

STEVEN SCHRAGA

November 1, 1999

Inventor's signature

Date

Residence

Surfside, Florida

Citizenship

US

Post Office Address

9433 Byron Avenue

Surfside, Florida 33154

Full name of second joint inventor, if any

Inventor's signature

Date

Residence

Citizenship

Post Office Address

(Supply similar information and signature for third and subsequent joint inventors.)